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Subject: Environmental Defense comments on Nitric Acid, 2-Ethylhexyl Ester (CAS# 27247-96-7)

(Submitted via Internet 6/15/04 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, MTC@mchsi.com, and Sarah_mclallen@americanchemistry.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for Nitric Acid, 2-Ethylhexyl Ester (CAS# 27247-96-7).

The American Chemistry Council Petroleum Additives Panel Health, Environmental, and Regulatory Task Group (HERTG) and its participating companies have submitted robust summaries and a test plan describing available data and proposed testing for nitric acid, 2-ethylhexyl ester to address SIDS elements required under EPA's High Production Volume Chemical Challenge. The test plan provides a very concise description of available data and proposed studies. Background information and available data are somewhat cursorily described in the test plan, but the data are described in much more detail in the robust summaries.

Nitric acid, 2-ethylhexyl ester is used primarily as a fuel additive in diesel fuels as to improve ignition and boost the cetane number of these fuels. Other uses, if any, are not mentioned. Since it is used in diesel fuels, this chemical possesses considerable potential for human and environmental exposure. Biodegradation data are not available. However, hydrolysis studies indicate that nitric acid, 2-ethylhexyl ester hydrolyzes in water at an appreciable rate, suggesting it should not accumulate in aquatic environments. Nitric acid, 2-ethylhexyl ester also appears to pose low hazard to aquatic organisms, as the EC50 values determined for fish, daphnia and algae are all in excess of its solubility in water. We note, however, the somewhat unusual finding that the toxicity of nitric acid, 2-ethylhexyl ester to each of the aquatic organisms studied decreased as the concentrations tested increased. These studies were conducted under GLP; however, these findings should be confirmed and an explanation provided.

Limited toxicity studies in mammals indicate that nitric acid, 2-ethylhexyl ester was not mutagenic when tested in the Ames system and is relatively non-toxic on acute oral or dermal administration. Descriptions of these studies in the test plan are somewhat cursory, however, and greater detail should be provided. For example, the mammalian species tested are not described on page 6 of the test plan, and significant data described in the robust summary, e.g., the low-level effects of nitric acid, 2-ethylhexyl ester administered in the diet, are not summarized in the test plan. Nitric acid, 2-ethylhexyl ester is apparently more toxic when administered by repeated doses, as the NOAEL in rats in a 28-day study was only 28 mg/kg/day. No data are available to address developmental/reproductive toxicity of this chemical, but appropriate studies are proposed.

Overall, the test plan appropriately proposes that each of the SIDS not currently addressed will be addressed by additional studies or by computer modeling.

Thank you for this opportunity to comment.

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